

Docket No.: 20345/0204389-US0
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Nahm Ryune Cho et al.

Application No.: Not Yet Assigned

Confirmation No.: N/A

Filed: Concurrently Herewith

Art Unit: N/A

For: **METHOD FOR PREPARING (S)-
INDOLINE-2-CARBOXYLIC ACID AND
(S)-INDOLINE-2-CARBOXYLIC ACID
METHYL ESTER USING HYDROLYTIC
ENZYME**

Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement accompanies the new patent application submitted herewith.

Applicant has not submitted copies of each cited U.S. patent and U.S. patent application as required by 37 CFR 1.98(a)(2)(i), amended October 2004, as the U.S. Patent and Trademark

Office has waived this requirement for all U.S. patent applications. Applicant submits herewith copies of foreign and non-patents in accordance with 37 CFR 1.98(a)(2).

Other information being provided for the examiner's consideration follows:

An International Search Report (ISR), mailed February 17, 2005; and an International Preliminary Report on Patentability (IPER) mailed March 16, 2006, both of which issued during the prosecution of International Application No. PCT/KR2004/002806, which corresponds to the present application.

Cite No. BB is not in the English language. In accordance with 1.98(c), Applicant states that a concise explanation of the relevance of document(s) DE 3727411 can be found on page 4 of the Specification; and

Cite Nos. BD through BG are not in the English language. The requirement for a concise explanation is satisfied by the aforementioned ISR and IPER.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Commissioner is authorized to charge any deficiency of up to \$300.00 or credit any excess in this fee to Deposit Account No. 04-0100.

Dated: May 26, 2006

Respectfully submitted,

/MARIE COLLAZO/
REG NO 44085

By _____
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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	Not Yet Assigned
				Filing Date	Concurrently Herewith
				First Named Inventor	Nahm Ryune Cho
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	1	of	1	Attorney Docket Number	20345/0204389-US0

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	AA*	US-4,614,806	09-30-1986	Buzby, Jr. et al.	
	AB*	US-4,898,822	02-06-1990	Asada et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	BA	EP-0 937 714	06-10-2004			
	BB	DE-3727411	03-24-1998			
	BC	EP-0197474	10-15-1986			
	BD	JP-06-16718	01-24-1994			
	BE	JP-07-79711	03-28-1995			
	BF	JP-07-79712	03-28-1995			
	BG	JP-61-92595	06-16-1986			

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	CA	M.Vincent et al., Tetrahedron Letters, Vol. 23, No. 16, pp 1677-1680, 1982	
	CB	Ryoichi Kuwano et al., J. Am. Chem. Soc. 2000, 122, 7614-7615	
	CC	Mahmoud Mahmoudian, et al. A practical enzymatic procedure for the resolution of N-substituted 2-azabicyclo[2.2.1]hept-5-en-3-one 10 (1999) 1201-1206	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY



(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PCT-E4176	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/KR2004/002806	International filing date (day/month/year) 03 NOVEMBER 2004 (03.11.2004)	Priority date (day/month/year) 26 NOVEMBER 2003 (26.11.2003)
International Patent Classification (IPC) or national classification and IPC C07D 209/42(2006.01)i		
Applicant SK CORPORATION et al		

- This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 4 sheets, including this cover sheet.
- This report is also accompanied by ANNEXES, comprising:
 - ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box relating to Sequence Listing (see Section 802 of the Administrative Instructions).

- This report contains indications relating to the following items:
 - ☒ Box No. I Basis of the report
 - ☐ Box No. II Priority
 - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - ☐ Box No. IV Lack of unity of invention
 - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - ☐ Box No. VI Certain documents cited
 - ☐ Box No. VII Certain defects in the international application
 - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand 15 APRIL 2005 (15.04.2005)	Date of completion of this report 16 MARCH 2006 (16.03.2006)
Name and mailing address of the IPEA/KR  Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer KIM, Il-ee Sue Telephone No. 82-42-481-5605 

Box No. 1 Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____ which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4)
- ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☒ the international application as originally filed/furnished
- ☐ the description:
- pages _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the claims:
- pages _____ as originally filed/furnished
- pages* _____ as amended (together with any statement) under Article 19
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the drawings:
- pages _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims	1-14	YES
	Claims	None	NO
Inventive step (IS)	Claims	1-14	YES
	Claims	None	NO
Industrial applicability (IA)	Claims	1-14	YES
	Claims	None	NO

2. Citations and explanations (Rule 70.7)

Reference is made to the following documents:

D1: EP 0197474 A1
D2: JP 06-16718 B2
D3: JP 61-92595 A1
D4: JP 07-79711 B2
D5: JP 07-79712 B2

The present invention relates to the preparation methods of (S)-indoline-2-carboxylic acid and methyl ester thereof using hydrolytic enzymes which can be used as an intermediate of a therapeutic agent for treatment of hypertension.

D1 relates to a process for preparing optically active indoline-2-carboxylic acid by hydrolyzing the racemic ester of (R,S)-indoline-2-carboxylic acid by means of an enzyme such as Bacillus and Aspergillus.

D2 discloses a method for preparing optically active indoline-2-carboxylic acid by using immobilized enzymes such as Bacillus and Aspergillus.

D3 describes a method for preparing optically active indoline-2-carboxylic acid ester by using enzymes like Bacillus and Aspergillus.

D4 relates to a process for preparing optically active indoline-2-carboxylic acid by using immobilized enzymes such as Aspergillus and Pseudomonas.

D5 relates to a process for preparing optically active indoline-2-carboxylic acid by an optical resolution.

1. Novelty

The subject matter of the present claims 1-14 is novel over the above D1-D5 and meets the criteria set out in PCT Article 33(2), because none of the prior art describes a method for preparing (S)-indoline-2-carboxylic acid and methyl ester thereof by reacting racemic indoline-2-carboxylic acid with methanol and thionyl chloride by means of a hydrolytic enzyme recited in the present claims.

See Supplemental Box for the next parts.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Box V.

2. Inventive step

The subject matter of the present claims 1-14 complies with PCT Article 33(3), since the prior art including the above D1-D5 does not teach or fairly suggest the following features: having a very high optical purity of at least 99%e.e.; simplifying preparation process; and having high preparation efficiencies by reacting racemic indoline-2-carboxylic acid with a low molecular weight alcohol, methanol, and thionyl chloride by means of a hydrolytic enzyme which is selected from the group consisting of Savinase, Alcalase, Novozym 243, Everlase, Esperase, Protease 7 and Acylase.

3. Industrial applicability

Claims 1-14 meet the criteria set out in PCT Article 33(4) and consequently, these claims are considered to be industrially applicable.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/KR2004/002806

A. CLASSIFICATION OF SUBJECT MATTER**IPC7 C07D 209/42**

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C07D 209/42, C12P 17/10, C12P 41/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean Patents and applications for inventions since 1975Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
CA on CD, eKIPASS, Delphion**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0197474 A2 (KANEKAFUCHI KAGAKE KOGYO KABUSHIKI KAISHA) 15 October 1986 See the whole document	1 - 14
A	JP 06-16718 B2 (KANEKAFUCHI CHEMICAL IND.) 09 March 1994 See the whole document	1 - 14
A	JP 61-92595 A (KANEKAFUCHI CHEMICAL IND.) 10 May 1986 See the whole document	1 - 14
A	JP 07-79711 B2 (KANEKAFUCHI CHEMICAL IND.) 30 August 1995 See the whole document	1 - 14
A	JP 07-79712 B2 (KANEKAFUCHI CHEMICAL IND.) 30 August 1995 See the whole document	1 - 14

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"B" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

16 FEBRUARY 2005 (16.02.2005)

Date of mailing of the international search report

17 FEBRUARY 2005 (17.02.2005)

Name and mailing address of the ISA/KR



Korean Intellectual Property Office
920 Dunsan-dong, Seo-gu, Daejeon 302-701,
Republic of Korea

Facsimile No. 82-42-472-7140

Authorized officer

JUNG, Jin Wook

Telephone No. 82-42-481-5609



INTERNATIONAL SEARCH REPORT

International application No.
PCT/KR2004/002806

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0197474 A2	15/10/1986	US 4898822 A JP 61282093 A2 JP 61265099 A2 JP 61227796 A2 DE 3680132 C0	06/02/1990 12/12/1986 12/11/1986 09/10/1986 14/08/1991
JP 06-16718 B2	09/03/1994	None	
JP 61-92595 A	10/05/1986	None	
JP 07-79711 B2	30/08/1995	None	
JP 07-79712 B2	30/08/1995	None	